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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

Yoshimura et al.

Serial No.: 10/594,627

Art Unit: 1711

Filed : July 16, 2007

Examiner: SERGENT, RABON A

Title : MEDICAL ADHESIVE

DECLARATION UNDER RULE 132

Honorable Commissioner of Patents and Trademarks,  
Alexandria, Virginia 22313-1450

Sir:

I, Tetsuji Yoshimura, a citizen of Japan and having postal mailing address of 4-7-13, Kitayamadai, Konan-shi, Shiga 520-3241 JAPAN, declare and say that:

March 1979, I graduated from Graduate School of Science, Kyoto University, and received a master's degree in chemistry;

From April 1979, up to the present, I have been employed by Sanyo Chemical Industries, Ltd., and engaged in the works of research and development for organic polymers, especially in the field of polyurethane;

In June 2003, I joined the group where the inventors of the present invention belonged;

I am the inventor of the above-identified application and am familiar with the technical field of the present invention;

I have read the Official Action mailed and the references cited therein. I respectfully submit herewith my exact report;

In order to demonstrate the effect of a combination of a urethane prepolymer obtained from a fluorine-containing nonaromatic polyisocyanate and a phenolic radical scavenger, I have carried out the following experiments under condition similar to that of Example 1 of the present application.

#### Comparative Example 7

100 parts of the random co-adduct of ethylene oxide/propylene oxide (b1) obtained in Production Example 1 was dehydrated under reduced pressure and nitrogen atmosphere at 100°C for 2 hours, followed by cooling to 50°C. Then, 0.5 parts of tetrakis-[methylene-3-(3',5'-di-t-butyl-4'-hydroxyphenyl)propionate]methane was added thereto as the phenolic radical scavenger (PRS) and the mixture was stirred uniformly for 30 minutes. After the mixture was cooled to 40°C, 8.7 parts of 2,4-tolylene diisocyanate (TDI) (the ratio of NCO group/OH group = 2/1) was added, and the resultant mixture was stirred uniformly and then heated to 80°C followed by a reaction at 80°C for 6 hours in order to obtain the medical adhesive (C7) for comparison. As for this (C7), the content of isocyanate groups was 1.9%, the number average molecular weight (Mn) was 5,600, and the content of alkaline metals and/or alkaline earth metals was 0.03 mmol/kg.

#### Comparative Example 8

100 parts of the random co-adduct of ethylene oxide/propylene oxide (b1) obtained in Production Example 1 was dehydrated under reduced pressure and nitrogen atmosphere at 100°C for 2 hours, followed by cooling to 50°C. Then, 0.5 parts of tetrakis-[methylene-3-(3',5'-di-

t-butyl-4'-hydroxyphenyl)propionate]methane was added thereto as the phenolic radical scavenger (PRS) and the mixture was stirred uniformly for 30 minutes. After the mixture was cooled to 40°C, 12.5 parts of 2,4'-diphenylmethane diisocyanate (MDI) (the ratio of NCO group/OH group = 2/1) was added, and the resultant mixture was stirred uniformly and then heated to 80°C followed by a reaction at 80°C for 6 hours in order to obtain the medical adhesive (C8) for comparison. As for this (C8), the content of isocyanate groups was 1.9%, the number average molecular weight (Mn) was 5,700, and the content of alkaline metals and/or alkaline earth metals was 0.03 mmol/kg.

#### Comparative Example 9

The medical adhesive (C9) for comparison was obtained by the same method as that in Comparative Example 8, except that the phenolic radical scavenger {tetrakis-[methylene-3-(3',5'-di-t-butyl-4'-hydroxyphenyl)propionate]methane} was not added. As for this (C9), the content of isocyanate groups was 1.9%, the number average molecular weight (Mn) was 5,700, and the content of alkaline metals and/or alkaline earth metals was 0.03 mmol/kg.

#### Comparative Example 10

100 parts of the random co-adduct of ethylene oxide/propylene oxide (b1) obtained in Production Example 1 was dehydrated under reduced pressure and nitrogen atmosphere at 100°C for 2 hours, followed by cooling to 50°C. Then, 0.5 parts of tetrakis-[methylene-3-(3',5'-di-t-butyl-4'-hydroxyphenyl)propionate]methane was added thereto as the phenolic radical scavenger (PRS) and the

mixture was stirred uniformly for 30 minutes. After the mixture was cooled to 40°C, 8.4 parts of hexamethylene diisocyanate (HDI) (the ratio of NCO group/OH group = 2/1) was added, and the resultant mixture was stirred uniformly and then heated to 80°C followed by a reaction at 80°C for 6 hours in order to obtain the medical adhesive (C10) for comparison. As for this (C10), the content of isocyanate groups was 1.9%, the number average molecular weight (Mn) was 5,600, and the content of alkaline metals and/or alkaline earth metals was 0.03 mmol/kg.

#### Comparative Example 11

The medical adhesive (C11) for comparison was obtained by the same method as that in Comparative Example 10, except that the phenolic radical scavenger {tetrakis-[methylene-3-(3',5'-di-t-butyl-4'-hydroxyphenyl)propionate]methane} was not added. As for this (C11), the content of isocyanate groups was 1.9%, the number average molecular weight (Mn) was 5,600, and the content of alkaline metals and/or alkaline earth metals was 0.03 mmol/kg.

#### Results

The medical adhesives (C7) to (C11) were evaluated by Evaluations 1 and 2 of the specification of the present application. The results are shown in Table 1. For comparison, results of Example 1 and Comparative Examples 1 and 6 are also shown.

Table 1

	Example	Comparative Example									
		1	6	7	8	9	10	11			
PRS	added	none	none	added	added	none	added	none			
Change in appearance	Excellent	Poor	Excellent	Excellent	Excellent	Excellent	Excellent	Excellent			
Wet adhesive strength (2H)	1.2	1.1	0.9	0.9	0.7	0.7	0.6	0.6			
Wet adhesive strength (5D)	1.3	-	0.8	0.8	0.7	0.7	0.5	0.5			

1) Comparing Comparative Examples 6 and 7, Comparative Examples 8 and 9, and Comparative Examples 10 and 11, respectively, the adhesives using the urethane prepolymers which were not obtained from fluorine-containing nonaromatic polyisocyanates maintained the sheet shapes at 5 days later, irrespective of presence of PRS. It means that there is no effect of presence of PRS.

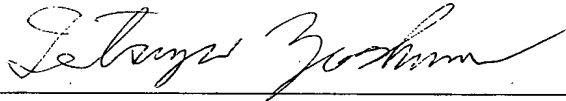
Concerning the wet adhesive strength, each of the adhesives showed almost no change in at 2 hours later and 5 days later, irrespective of presence of PRS. Moreover, it is lower than that of the present invention. It means that presence of PRS does not affect continuity of the wet adhesive strength.

2) Concerning Comparative Example 1, the urethane prepolymer obtained from fluorine-containing nonaromatic polyisocyanates was used but PRS was not used. The adhesive could not maintain the sheet shape at 5 days later. The wet adhesive strength was high at 2 hours later, but could not be measured at 5 days later since a viscous liquid formed.

3) Concerning Example 1, both the urethane prepolymer obtained from fluorine-containing nonaromatic polyisocyanates and PRS were used. The adhesive maintained the sheet shape at 5 days later. The wet adhesive strength was high both at 2 hours later and at 5 days later.

I declare further that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Signed this                      day of                      12.12 , 2007

A handwritten signature in cursive script, appearing to read 'Tetsuji Yoshimura', is written over a horizontal line.

Tetsuji Yoshimura